UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,485	05/24/2006	Joachim Moormann	RO4246US (#90568)	2532

7590 06/30/2009

Sean F Mellino
D Peter Hochberg
1940 East 6th St-6th Floor
Cleveland, OH 44114

EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,485	MOORMANN ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *16-24 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 25-40* is/are rejected.

7)☒ Claim(s) *2 and 39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Applicants' amendments and remarks, filed 11 March 2009 regarding Application N° 10/580,485, are acknowledged and entered on the record. The Examiner acknowledges the following:

Claims 1-40 are pending, where claims 16-24 and 38 remain presently withdrawn from consideration.

No claims have been cancelled.

Claims 39 and 40 are added as new claims. Support for the claims is derived from the originally submitted claims.

Claims 1, 2, 5, 8, 12, 14, and 26 have been amended. Independent claim 1 has been amended to recite that the medicament comprises a slow- and a fast-dissolving layer, both of which contain active substances. Applicants provide support for the amendment. Claims 1 and 2 have also been amended to clarify the Markush language. Claim 5 is amended to remove the narrower limitations of two- and three-layered structures from the claim. Claim 8 has been amended to remove the broader recitation of "or has at least one mucoadhesive outer surface" from the claim. Claim 12 has been amended to remove the limitations "has a depot effect" and "with a delay time" from the claim. The scope of claim 14 is amended by removing the term "not" and adding the limitation "acetylcholinesterase inhibitors and opiate antagonists". Support for this amendment is provided. Claim 26 is amended (i.e. edited).

No new matter has been added.

RESPONSE TO RESTRICTION REMARKS

Regarding Applicants' remarks to the lack of unity restriction requirement made in view of Asmussen (USPN 6,599,511), the Examiner acknowledges that Applicants **continue to traverse** the previously elected Group I (claims 1-15 and 25-37), which now also includes claims 39 and 40, for the reasons already made of record.

Applicants' arguments filed 20 March 2009 have been fully considered but they are not persuasive, primarily because the cited art reads on using at least one active agent as recited in claim 1 (e.g. deoxypeganine) in the form of an oral, film shaped medicament (Abstract). The active is taught as comprising between 0.1 and 50% by weight of the therapeutic system (col. 2, lines 61-65) and is taught being released over long periods of time ranging from 12-72 hours. Though the content of the drug is not expressly taught in terms of mg, it is within the purview of the ordinarily skilled artisan ascertain the amount of drug in mg based on the percent weight of the overall system. Furthermore, initial release of the drug occurring between 1-6 hours though not expressly taught is within the scope of time release which is taught (col. 2, lines 10-15).

Applicants' election is thus made **FINAL**. The remaining claims Group II (claims 16-24 and 38) remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions and/or species, there being no allowable generic or linking claim. Applicants once again, timely traversed the restriction requirement between the composition and the method (i.e. "use" claims).

Thus, claims 1-15 and 25-40 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicants' amendment to the Abstract of the Invention has been considered fully and is persuasive. Thus, said objection has been **withdrawn**.

Rejections under 35 USC 112

Applicants' amendment to claim 14, as discussed above, renders moot the written description rejection, under 35 USC 112, first paragraph. Thus, said rejection has been **withdrawn**.

Applicants' amendments to clarify claims 1 and 2, as discussed above, renders moot the indefiniteness rejection, under 35 USC 112, second paragraph. Thus, said rejection has been **withdrawn**.

Applicants' remarks regarding the lack of antecedent basis rejection to claim 6, have been reconsidered by the Examiner and are persuasive, thereby rendering moot the rejection, under 35 USC 112, second paragraph. Thus, said rejection has been **withdrawn**.

Applicants' amendment to claim 12, as discussed above, renders moot the indefiniteness rejection, under 35 USC 112, second paragraph. Thus, said rejection has been **withdrawn**. Claim 37, which was originally rejected as depending from the rejected claim 12, remains so rejected because of the amendment which was made to claim 12 (see **NEW REJECTION** section below).

Applicants' amendments to claims 5 and 8, as discussed above, renders moot the rejection made on the grounds a broader limitation being concurrently recited with a narrower limitation, under 35 USC 112, second paragraph. Thus, said rejections both stand **withdrawn**.

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Correspondence dated 28 November 2008 since the art which was previously cited continues to read on the amended limitations.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 14, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmussen et al. (US Pre-Grant Publication N° 2007/0190117) in combination with Asmussen et al. (USPN 6,599,511).

The instant claims are drawn to an orally administered, film-shaped medicament containing at least one of the active substances: deoxypeganine and a deoxypeganine derivative such as an acid salt derivative (claims 1, 2 and 25). Claims 3 and 26 further limits the dosage form to an oral transmucosal (i.e. buccal) administration form. The structure of the dosage form is recited as having multiple layers (claim 5). Claim 14, as discussed above, further limits the composition of claim 1 such that it additionally contains a non-deoxypeganine-based active substance, such as galanthamine.

The Pre-Grant Publication to Asmussen (also herein referred to as the '117 application) expressly teaches a film-shaped medicament for buccal administration of galanthamine and at least one further pharmaceutically active substance, which is preferably selected from the group comprising acetylcholinesterase inhibitors (Abstract and claim 10). The Abstract and claim 7 also teach that the film-shaped medicament has a bilayer or multilayer structure, wherein at least one of the layers contains the active substance. However, the '117 application does not further teach any

specific examples acetylcholinesterase inhibitors which may be incorporated into said film-shaped dosage form.

The '511 patent to Asmussen et al. expressly teaches using the compound desoxypeganine (1,2,3,9-tetrahydropyrrolo[2,1-b] quinazoline; deoxypeganine), which is a noted inhibitor of acetylcholinesterase (col. 1, lines 42-52), in orally, transdermally or sublingually (e.g. buccal) administered pharmaceutical preparations (claim 6 and col. 1, lines 18-20). Claim 6 further teaches that the desoxypeganine-based active compound consists of desoxypeganine and/or a pharmaceutically acceptable salt thereof such as the hydrochloride salt (col. 1, line 63 to col. 2, line 3). The dosage form is further taught as comprising multiple layers, including a reservoir layer containing said desoxypeganine-based active substance(s) (claim 10 and col. 2, lines 38-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a buccally-administrable, film-shaped dosage form comprising an acetylcholinesterase inhibitor such as deoxypeganine and/or its hydrochloride salt, and at least one other non-deoxypeganine-based active compound such as galanthamine as taught and suggested by Asmussen ('117) and Asmussen ('511).

Since both of the inventions to Asmussen overlap in their teachings, as discussed above, one of ordinary skill in the art would have been particularly motivated to prepare the instantly claimed composition. Thus, it would have been *prima facie* obvious to combine the teachings provided by the two dosage forms, each of which are taught by the art as being useful for the same purpose, in order to form a third composition, such as that which is instantly claimed, to be used for the very same purpose; the idea of combining them flowing logically from their having been

individually taught in the prior art (MPEP §2144.06). In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)

Claims 4, 6-13, 15 and 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Asmussen et al. ('117) and Asmussen et al. ('511).

With respect to claims 1-3, 5, 14, 25 and 26, already discussed above, claims 4, 6, and 27-29 recite percent weight limitations for the deoxypeganine-based active substance(s) within the reservoir layer (claims 4, 27 and 28) and/or the dosage form as a whole (claims 6 and 29).

Asmussen ('117) expressly teaches in claim 2 that the active substance resides in a reservoir within at least one of the layers at a particularly preferred percent range of 20-50% by weight. Claim 9 teaches that the active substance content of the dosage form is preferably between 1-20% by weight of the form. However, the '117 application does not expressly teach that the acetylcholinesterase inhibitor active compounds contribute to these percentages or if they do, it is not expressly taught how much is attributed to said inhibitors.

Asmussen ('115) on the other hand, expressly teaches the multilayered dosage form as comprising a preferred percent weight range of 5-20% by weight of the desoxypeganine-based active (col. 2, lines 61-65). Since only one reservoir layer is described in the delivery device, said layer containing the desoxypeganine-based drug, it then follows that the overall device contains the claimed amount of active as well.

The primary reference ('117) does not expressly teach the percent weight ranges of desoxypeganine-based active either within the reservoir layer or the overall medicament, as claimed by Applicants. However, since the values and formats of each parameter with respect to

the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. In the instant case, under the guidance of the '511 patent, which teaches the presence of the desoxypeganine-based active in the compositional percentages as instantly claimed, it would have been *prima facie* obvious to customize the amount of acetylcholinesterase inhibitor within the film-shaped galanthamine medicament ('117) such that the levels of desoxypeganine-based active of the instantly claimed medicament were met. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of this parameter would have been obvious at the time of Applicants' invention.

With respect to claims 1-3, 5, 14, 25 and 26, already discussed above, limitations to the overall thickness of the film composition are recited (claims 7, 30 and 31). The composition is recited as being mucoadhesive (claim 8). The composition is recited as being soluble in an aqueous media such as saliva (claims 9, 32, 33 and 36). With regard to the limitations recited in claims 9 and 33, which respectively state that "dissolution takes place between 1 second and 5 minutes" and "…between 3-30 seconds"; until some material difference in the properties of the composition is demonstrated, said limitations are considered by the Examiner to be directed toward the film-shaped formulation, which is instantly claimed. The composition is also recited as being disintegratable in an aqueous media such as saliva (claims 10, 34 and 35). Similar to the dissolution property, regarding the limitations of claims 10 and 35wherein "dissolution takes place between 1 second and 5 minutes" and "…between 3-30 seconds"; until some material difference

in the properties of the composition is demonstrated, said limitations are considered by the Examiner to be directed toward the film-shaped formulation, which is instantly claimed. Claims 12 and 37, as discussed above, recite that the active agent is released between 8-24 hours. Claim 13 further limits the composition of claim 1 such that it comprises at least one active rapid-release layer and at least one active delayed-release layer. Claim 15 recites that the composition of claim 1 further contains at least one auxiliary substance (i.e. excipients, additives, etc.).

Asmussen ('117) expressly teaches the following of Applicants' claimed parameters:

- that the flat film-shaped medicaments are taught as having a preferred layer thickness in the range of 0.01-5 mm ¶[0023],
- preferred embodiments of the film-shaped dosage form are taught whereby said preparations are characterized as being mucoadhesive and soluble in aqueous media, being mucoadhesive and disintegratable in aqueous media, or being mucoadhesive and capable of gelling or swelling in aqueous media ¶[0041],
- aqueous media is further taught as being physiological media and is understood to mean water and physiological media such as saliva ¶[0038],
- disintegration time for the dosage form is taught as being between 10 seconds and 12 ¶[0042],
- the active substance-containing layer of the wafers, or at least one of the layers is taught as having a delayed active release ranging up to a preferred duration of 24 hours ¶[0050],

- having an outer release layer which is followed distally (i.e. away from the buccal contact surface) by at least one further layer which preferably exhibits a retarded active substance release ¶[0051],
- the film-shaped medicament is further characterized such that it contains one or more auxiliaries such as fillers, colorants, emulsifiers, plasticizers, disintegration promoters, disintegrants (wick agents), wetting agents, sweetening and flavoring agents, preservatives, pH regulators, permeation-enhancing substances and antioxidants (claim 12 and ¶¶[0053]-[0055])

In view of the combined teachings of Asmussen '117 and '511, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a film-shaped dosage form comprising a deoxypeganine-based active and at least one other active such as galanthamine as taught and suggested by Asmussen ('117) and Asmussen ('511), and format the structure of said dosage form as expressly taught by Asmussen ('117), to produce the instantly claimed composition.

Since both of the inventions to Asmussen overlap in their teachings, as discussed above, one of ordinary skill in the art would have been motivated to prepare the instantly claimed composition, and would have been particularly motivated to incorporate compounds such as deoxypeganine hydrochloride into the invention practiced by Asmussen ('117) alongside a non-deoxypeganine compound such as galanthamine, as active substances for the resulting oral film-shaped dosage form. Thus, it would have been *prima facie* obvious to combine the teachings provided by the two dosage forms, each of which are taught by the art as being useful for the same

purpose, in order to form a third composition, such as that which is instantly claimed, to be used for the very same purpose; the idea of combining them flowing logically from their having been individually taught in the prior art (MPEP §2144.06). In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)

From the teachings of the combined references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1-15 and 25-37 under 35 USC 103(a) as being unpatentable over the combined teachings of Asmussen et al. (US Pre-Grant Publication N° 2007/0190117) and Asmussen et al. (USPN 6,599,511), have been fully considered but they are not persuasive.

Applicants allege that the '117 publication fails to teach or suggest the use of any other active substance other than galanthamine or its derivatives and thus fails to teach or suggest the use of deoxypeganine in a medicament as well as a medicament with a rapidly and slowly disintegrating active substance containing layer in accordance with the presently amended claim 1. Applicants further allege that the '511 reference, while specifically teaching the use of deoxypeganine, actually teaches away from the instantly claimed invention since the controlled release of the drug is preferably directed to transdermal delivery.

In response to Applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, the Examiner respectfully disagrees with Applicants' arguments and maintains that the instantly claimed invention, as amended in claim 1, continues to be taught by the combined references. Of particular note are the teachings of claims 1, 8 and 10 in the '117 publication. Claim 1, as Applicants correctly point out, teaches that the film-shaped buccal medicament comprises a rapid release layer as one of its multiple layers. Said rapid release layer comprises the galanthamine et al. Claim 10 further teaches that galanthamine et al. is further combined with at least one other pharmaceutical active substance, preferably an acetylcholinesterase inhibitor. Claim 8 expressly teaches that at least one of the layers taught in claim 1, demonstrates retarded active substance release. As previously acknowledged, the '117 publication does not expressly teach deoxypeganine et al. as one of the additional preferred acetylcholinesterase inhibitors. However, as discussed above the '511 reference does expressly teach the incorporation of desoxypeganine into a controlled-release oral transdermal formulation (Abstract) and that desoxypeganine inhibits acetylcholinesterase (col. 1, lines 51-52). Thus, in view of the *combined* Asmussen teachings, the ordinarily skilled artisan would have been highly motivated to: 1.) prepare a multilayered film-shaped buccal administration form where at least one layer rapidly releases the active(s) and at least one other layer slowly releases the active(s); 2.) infuse galanthamine and at least one other acetylcholinesterase inhibitor together into each of the layers of the buccal film; and lastly, 3.) to look to the '511 reference for guidance in selecting

desoxypeganine as the additional preferred acetylcholinesterase inhibitor [*emphasis added*].

For these reasons, Applicants' arguments are found unpersuasive. The above rejection is hereby **maintained** as well as extended to new claims 39 and 40, since the subject matter recited therein is expressly taught by the combined references. The Examiner points to the teachings of Asmussen ('117), as discussed above, which expressly teach the inclusion of both citric and malic acids and combinations thereof.

NEW OBJECTIONS/REJECTIONS

In light of Applicants' amendments, most notably to claim 1, as well as the newly added claims 39 and 40, the following rejections have been newly added:

CLAIM OBJECTIONS

Claims 2 and 39 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, both claims expand the scope of the claimed active agent to include "pharmaceutically acceptable salts of deoxypeganine and pharmaceutically acceptable salts of a derivative of deoxypeganine".

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "said at least one active substance is selected from the group consisting of pharmaceutically acceptable salts of deoxypeganine and pharmaceutically acceptable salts of a derivative of deoxypeganine". There is insufficient antecedent basis for the "salt" limitations in claim 1.

Claim 12, as discussed above, has been amended such that the limitation reciting "with a delay in time" has been removed. Claim 37, as a result of this amendment, now lacks sufficient antecedent basis to claim 12, since it continues to recite the limitation "said delay in time…".

All claims have been rejected; no claims are allowed.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615